K040181

MAR 2 4 2004

510(k) Summary

1.0 Submitted By:

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2.0 Date Submitted

January 26, 2004

3.0 Device Name(s):

3.1 Proprietary Names
Access® DHEA-S Reagent
Access® DHEA-S Calibrators

3.2 Classification Names
Dehydroepiandrosterone (free and sulfate) test system (21 CFR § 862.1245)
Calibrator (21 CFR § 862.1150)

4.0 Legally Marketed Device

Candidate(s)	Predicate	Manufacturer	Docket Number
Access DHEA-S Reagent	Immulite DHEA-SO4 Reagent	Diagnostic Products, Corp.*	K935806
Access DHEA-S Calibrators	Access Ultrasensitive hGH Calibrators	Beckman Coulter, Inc.	K003098

*Diagnostic Products, Corp., Los Angeles, CA
**Beckman Coulter, Inc., Chaska, MN

5.0 Device Description

The Access® DHEA-S Reagent is designed for optimal performance on the Access family of immunoassay systems, including the Access, Access 2, UniCel™ DxI 800, and SYNCHRON LX®i 725 clinical analyzers. The Access Immunoassay Systems utilize a competitive binding immunoenzymatic method for quantitative analyte measurement. The Access DHEA-S Reagent kit contains two 50-test reagent packs and is packaged separately from the associated calibrators. The Access DHEA-S Calibrators are designed for use with the Access DHEA-S Reagent for generation of the DHEA-S assay calibration curve on Beckman Coulter's Access Immunoassay Systems. The Access DHEA-S Calibrator kit contains 6 X 2 mL bottles, one for each of six calibrator levels.

6.0 Intended Use

The Access DHEA-S assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of Dehydroepiandrosterone sulfate levels in human serum and plasma using the Access Immunoassay Systems. The Access DHEA-S Calibrators are intended to calibrate the Access DHEA-S assay for the quantitative determination of Dehydroepiandrosterone sulfate levels in human serum and plasma using the Access Immunoassay Systems.

7.0 Comparison to the Predicate

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary:

	Similarities	
Access DHEA-S Reagent	Intended Use	Same as Diagnostic Products Immulite DHEA-SO4 Reagent
	Methodology	
	Antibody source (rabbit)	
	Chemiluminescent substrate	
	Liquid-stable reagents	
	Differences	
	Sample Type	DHEA-S: Serum, Plasma DHEA-SO4: Serum
	Sample Volume	DHEA-S: 10 µL DHEA-SO4: 5 µL
	Reportable Range	DHEA-S: 2 – 1000 µg/dL DHEA-SO4: 15 – 1000 µg/dL
	Analytical Sensitivity	DHEA-S: 2 µg/dL DHEA-SO4: 3 µg/dL
	Calibrator Matrix	DHEA-S: Liquid-stable DHEA-SO4: Lyophillized
	Calibration Scheme	DHEA-S: 6-point curve DHEA-SO4: 2-point adjustment

The Access DHEA-S Calibrators and the predicate calibrator utilize the same test methodology specific to Access Immunoassay Systems. Each calibrator is intended for use in a different analyte test system. Both calibrators are derived from a stabilized bovine serum albumin preparation. The Access DHEA-S Calibrators are liquid stable while the predicate calibrator is lyophilized and requires preparation.

8.0 Summary of Performance Data

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Assay equivalence is demonstrated through method comparison, linearity, and imprecision experiments.

Access DHEA-S Method Comparison Study Results

Candidate Method	Slope	Intercept	r	n	Predicate Method
Access DHEA-S Assay	1.028	6.6	0.993	263	Immulite DHEA-SO4 Assay

Access DHEA-S Estimated Imprecision

Sample	Mean (µg/dL)	S.D. (µg/dL)	%C.V.	N
Within-Run Imprecision				
Level 1	10.3	0.86	8.3	80
Level 2	34.4	1.10	3.2	80
Level 3	123.9	5.90	4.8	80
Level 4	347.3	8.92	2.6	80
Level 5	736.1	12.10	1.6	80
Total Imprecision				
Level 1	10.3	1.16	11.3	80
Level 2	34.4	1.76	5.1	80
Level 3	123.9	7.99	6.4	80
Level 4	347.3	15.40	4.4	80
Level 5	736.1	27.20	3.7	80

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 4 2004

Ms. Mary Beth Tang
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Re: k040181
Trade/Device Name: Access® DHEA-S Reagent and Calibrators
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT; JKC
Dated: January 26, 2004
Received: January 27, 2004

Dear Ms. Tang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K040181**

Device Name: **Access® DHEA-S Reagent and Calibrators**

Indications For Use:

The Access DHEA-S assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of Dehydroepiandrosterone sulfate levels in human serum and plasma using the Access Immunoassay Systems.

Measurement of dehydroepiandrosterone sulfate may be used in the differential diagnosis of Cushing's syndrome, as well as in the evaluation of adrenocortical diseases, such as congenital adrenal hyperplasia and adrenal tumors. In hirsute female patients, increased DHEA-S levels have been associated with virilizing adrenal tumors. Patients with polycystic ovary syndrome have often demonstrated elevated levels of DHEA-S, suggesting an adrenal androgen contribution to the defect in this disorder.

The Access DHEA-S Calibrators are intended to calibrate the Access DHEA-S assay for the quantitative determination of Dehydroepiandrosterone sulfate levels in human serum and plasma using the Access Immunoassay Systems.

Prescription Use ___X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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